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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/765,720	06/20/2007	GEROLD SCHULER	106985-5 (2)	8028
27384 7590 05/26/2009 NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022				
EXAMINER				
JUEDES, AMYE				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
05/26/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

11/765,720

**Applicant(s)**

SCHULER ET AL.

**Examiner**

AMY E. JUEDES

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/3/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendment and remarks, filed 3/3/09, are acknowledged.  
Claims 29-30 have been amended.  
Claims 29-32 are pending, and are under examination.
2. Applicant's amendment to the drawings, replacing figure 4B, and cancelling previous sheets 5-7, is acknowledged. The replacement fig 4B is acceptable, and the objection to the drawings is withdrawn.
3. Upon reconsideration, and in view of Applicant's remarks, the rejection of the claims under 35 U.S.C. 112 first paragraph for new matter is withdrawn.
4. The rejection of the claims under 35 U.S.C. 102(a) as being anticipated by Jonuleit et al. is withdrawn in view of Applicant's declaration under 37 CFR 1.131. Applicant demonstrates completion of the same invention disclosed by Jonuleit et al. prior to April 1, 2002.
5. The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by Levings et al. is withdrawn in view of Applicant's amendment to recite that the CD4+CD25+ T cells are isolated from human "peripheral blood". The CD4+ suppression assays taught by Levings et al. were performed using CD4+CD25+ T cells isolated from umbilical cord blood.
6. The following are new grounds of rejection necessitated by Applicant's amendment.
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Groux et al., 1997, as evidenced by Ng et al., 2001 (of record).

Groux et al. teach a method of suppressing autologous (i.e. syngeneic) human CD4 T cell proliferation comprising co-culturing said CD4 T cells with IL-10 producing human Tr1 regulatory T cells ex vivo (see page 739 and Fig. 3 in particular). Groux et al. also teach producing the Tr1 regulatory T cells by isolating CD4+ T cells from human peripheral blood and culturing said CD4+ T cells ex-vivo (see page 741, in particular). As evidenced by Ng et al., peripheral blood CD4+ T cells comprise both CD25+ and CD25 negative subsets (see page 2738, in particular). Thus, Groux et al. have inherently isolated both CD4+CD25+ and CD4+CD24- T cells from peripheral blood. Furthermore, by culturing the total CD4+ T cells population to produce the Tr1 regulatory T cells, Groux et al. have inherently contacted and anergized CD4+CD25- T cells with CD4+CD25+ T cells, as recited in the instant claims.

Thus, the reference clearly anticipates the invention.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes  
Patent Examiner  
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Examiner, Art Unit 1644